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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,774	02/07/2005	Nobutaka Wakamiya	19036/40320	5088

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,774	WAKAMIYA ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9 and 11-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9 and 11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 25 October 2007. Claims 5, 10 and 18-40 have been cancelled. Claims 1-5, 6-9 and 11-17 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. §119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Initialed and dated copy of Applicant's IDS form 1449, filed on 25 October 2007, is attached to the instant Office action

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claim 38 under 35 U.S.C. §101 as directing to non-statutory subject matter is **withdrawn** in response to Applicants' amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-17 and 38 under 35 U.S.C. §102(b) as being anticipated by Ezekowitz *et al.* (1989) is **withdrawn** in response to Applicant's amendment adding a new limitation, "a recombinant human mannose binding protein."

New Rejections

Claims 1-4, 6-9 and 11-17 are rejected under 35 U.S.C. §102(b) as being anticipated by Ezekowitz (US PAT NO. 5,270,199, issued 14 December 1993).

Claim 1 is directed to an anti-HIV agent which comprises a recombinant human mannose binding protein (MBP) as an active component. Claims 2-4 are drawn to a recombinant human MBP having HIV neutralization and HIV budding suppressive activity. Claims 6 and 7 are product-by-process claims of a recombinant human MBP from various sources. Claims 8, 9 and 11-17 are drawn to a recombinant human MBP suppressing HIV of different tropisms, subtypes, and a specific strain.

Ezekowitz teach recombinant human MBP (col. 2, lines 51-64) that can inhibit HIV by lowering the rate of infection of eukaryotic cells (col. 3, lines 27-41).

Since it is widely known in the art that the ligand for MBP binding is the mannose oligosaccharides on gp120 and that gp120 is present in every strain of HIV-1 regardless of the cell tropism and subtype, the MBP must inherently inhibit every subtype or strain of HIV of any kind of tropism in claims 8, 9 and 11-17. Where applicant claims a product in terms of a characteristic not explicitly disclosed by the reference, a §102 or

§103 rejection is proper. The instant invention additionally claims the following properties:

(1) wherein said MBP has HIV proliferation suppressive activity, which is HIV neutralizing activity and HIV budding suppressive activity (claims 2-4);

(2) wherein said HIV is an HIV strain belonging to Subtype B of Group M of HIV Type 1 (claim 8);

(3) wherein said HIV is an HIV strain belonging to Subtype D of Group M of HIV Type 1 (claim 9);

(4) wherein said HIV is a CRF01_AE (claim 11); and

(5) wherein said HIV has tropism toward both CCR5 and CXCR4, in other words, wherein said HIV has tropism toward both macrophages and T cells (claims 12-17).

A rejection under 35 U.S.C. §102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic (MPEP §2112). According to M.P.E.P. § 2112 [R-3], "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentable." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Newly discovered property of prior art cannot support patent on that same art. See MPEP §2112 [R-3]. *Abbott Laboratories v. Baxter Pharmaceutical Products Inc.* 80 USPQ2d 1860, U.S. Court of Appeals Federal Circuit Nos. 06-1021, -1022, -1034. Thus the claiming of a new use, new function or unknown property which is inherently present in

the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1251, 1254, 195 USPQ 430, 433 (CCPA 1977).

Therefore, the recombinant human MBP taught by Ezekowitz anticipates the recombinant human MBP in the claimed invention and would necessarily anticipate the claimed properties and advantages that are readily recognized by persons of skill in the art.

Claims 6 and 7 are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2113: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by- process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695,698,227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Since Ezekowitz teach the claimed MBP, the MBP from different sources in claims 5-7 are anticipated.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989). Patent owner's burden under the circumstances presented herein was described in *In re Best*, 562 F.2d 1252,

1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. §102, on 'prima facie obviousness' under 35 U.S.C. §103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Absent evidence to the contrary, it appears that the recombinant human MBP taught by Ezekowitz anticipates the instantly claimed invention. Applicants need to provide objective evidence to distinguish the claimed invention from the cited prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
21 December 2007

Louise Humphrey, Ph.D.
Assistant Examiner